Citation:

Nuñez-Cordoba JM, Alonso A, Beunza JJ, Palma S, Gomez-Gracia E, Martinez-Gonzalez MA. Role of vegetables and fruits in Mediterranean diets to prevent hypertension. *Eur J Clin Nutr*. 2009 May; 63 (5): 605-612.

PubMed ID: 18301434

Study Design:

Prospective Cohort Study

Class:

B - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To assess the relationship between the consumption of fruits and vegetables and the incidence of hypertension (HTN) in a prospective Mediterranean study.

Inclusion Criteria:

Alumnus of the University of Navarra or other university graduate in Spain.

Exclusion Criteria:

- Reported cardiovascular disease at baseline
- Had high blood pressure, a medical diagnosis of HTN or was using anti-hypertensive medication
- Reported extreme caloric intake or had missing data for some of the covariates.

Description of Study Protocol:

Recruitment

A mailed questionnaire was sent to all University of Navarra and other university graduates in Spain as part of the Seguimiento University of Navarra Project, a dynamic cohort that began recruitment in 1999.

Design

Prospective cohort study.

Dietary Intake/Dietary Assessment Methodology

A semi-quantitative food-frequency questionnaire (FFQ) (validated in Spain) was used, which included 13 fruit items and 11 vegetable items to calculated the total servings per day of fruit and vegetables.

Blinding Used

Not applicable.

Intervention

Not applicable.

Statistical Analysis

- Multivariable Cox regression was used to calculate hazard ratios (HR) for HTN (based on cumulative incidence rates) by comparing each category of fruit and vegetable intake with respect to the lowest intake (less than one serving per day)
- Linear trends were assessed using Cox regression with the median intake for each category used as a continuous variable
- Stratified analysis and interaction was also assessed.

Data Collection Summary:

Timing of Measurements

After the baseline assessment questionnaire, participants received biennial mailed follow-up questionnaires.

Dependent Variables

Hypertension status (self-reported).

Independent Variables

- Servings per day of fruits and vegetables
- Servings per day of fruits
- Servings per day of vegetables.

Control Variables

- Age
- Gender
- Body mass index (BMI)
- Total energy intake
- Physical activity
- Alcohol intake
- Family history of HTN
- Sodium intake
- Low-fat dairy intake
- Whole grain intake
- Fish intake
- Smoking status.

Description of Actual Data Sample:

- *Initial N:* Of a total of 13,631 participants recruited at least two years ago, 10,940 completed follow-up assessments
- *Attrition (final N):* 8,594 (after applying exclusion criteria; 3,256 men and 5,338 women)
- *Age:* Mean of 41.1 years (range, 20-95 years)
- *Ethnicity:* Not reported
- *Other relevant demographics:* University graduates
- *Anthropometrics:* None
- *Location:* Spain.

Summary of Results:

Key Findings

- There was no statistically significant association between HTN and servings per day of vegetables or servings per day of fruits
- There was a significant inverse association between fruit and vegetable consumption and the risk of HTN only among participants with a low olive oil consumption (<15g per day). The test for trend in this group was significant (0.008). Compared to those who ate no more than two servings of fruits and vegetables daily, those who ate at least five per day had a lower risk of HTN (hazard ratio=0.56 (95% confidence interval: 0.35, 0.89).

Author Conclusion:

There is a beneficial inverse association between servings per day of fruit and vegetables (at least five per day) and the incidence of HTN in participants with a lower consumption of olive oil.

Reviewer Comments:

Strengths

- *Median follow-up of 49 months*
- *Analysis controlled for many covariates and assessed interaction.*

Limitations

Self reported HTN status, dietary intake, weight and leisure-time physical activity.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions

1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes

2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	N/A
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes

3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	N/A
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	No
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	N/A
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	N/A
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	N/A
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	Yes
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes

6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	N/A
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes

9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes